

[0090] The target fill volume was set at 1.19 mL for this procedure. 160 syringes (in two tubs of 80 syringes each) were filled with each of the three different formulated substances. Deliverable volumes from 10 successfully filled and stoppered syringes from each batch were then measured. Deliverable volumes were measured by expelling volume from each syringe, weighing the expelled volume, and converting the weight to volume using the densities noted in Table 5. Deliverable volumes were calculated to be as follows:

TABLE 9

Condition	Avg. Vol. (mL)	Max. Vol. (mL)	Min. Vol. (mL)
87.7 mg/mL antibody A (Tub 1 of 2)	1.19	1.23	1.15
87.7 mg/mL antibody A (Tub 2 of 2)	1.18	1.22	1.17
131.6 mg/mL antibody A (Tub 1 of 2)	1.18	1.21	1.16
131.6 mg/mL antibody A (Tub 2 of 2)	1.18	1.18	1.15
175 mg/mL antibody A (Tub 1 of 2)	1.17	1.20	1.15
175 mg/mL antibody A (Tub 2 of 2)	1.16	1.17	1.15

[0091] As can be seen by comparing these volumes to those in Table 6, deliverable volumes of hand-filled syringes were comparable to deliverable volumes of machine-filled syringes.

[0092] Stoppering heights were measured for 15 hand-filled samples using Vernier calipers, and were taken, from the top of the stopper to the distal side of the syringe flange. Measurements were as follows:

TABLE 10

Condition	Avg. Stop-pering Height (mm)	Max. Stop-pering Height (mm)	Min. Stop-pering Height (mm)
87.7 mg/mL antibody A (Tub 1 of 2)	5.7	6.0	5.4
87.7 mg/mL antibody A (Tub 2 of 2)	5.6	6.2	5.4
131.6 mg/mL antibody A (Tub 1 of 2)	6.2	6.6	6.0
131.6 mg/mL antibody A (Tub 2 of 2)	6.0	6.2	5.8
175 mg/mL antibody A (Tub 1 of 2)	6.2	6.8	6.0
175 mg/mL antibody A (Tub 2 of 2)	6.3	6.7	6.2

[0093] As can be seen by comparing these stoppering heights to those in Table 7, stoppering heights of hand-filled syringes were comparable to stoppering heights of machine-filled syringes.

[0094] The above description and examples are illustrative, and are not intended to be restrictive. One of ordinary skill in the art may make numerous modifications and/or changes without departing from the general scope of the invention. For example, and as has been described, the above-described embodiments (and/or aspects thereof) may be used in combination with each other. Additionally, portions of the above-described embodiments may be removed without departing from the scope of the invention. In addition, modifications may be made to adapt a particular situation or material to the teachings of the various embodiments without departing from their scope. Many other embodiments will also be apparent to those of skill in the art upon reviewing the above description.

[0095] The term “about” as used herein with respect to a value may refer to a variation of 10% above or below the

stated value. Additionally, while a number of objects and advantages of the embodiments disclosed herein (and variations thereof) are described, not necessarily all such objects or advantages may be achieved in accordance with any particular embodiment. Thus, for example, those skilled in the art will recognize that the systems and techniques described herein may be embodied or carried out in a manner that achieves or optimizes one advantage or group of advantages as taught herein without necessarily achieving other objects or advantages as may be taught or suggested herein.

What is claimed is:

1. A method of preparing a drug product, comprising: introducing a volume of a formulated drug substance into a primary packaging component, wherein the volume of the formulated drug substance is greater than a nominal volume of the primary packaging component; and positioning a stopper within the primary packaging component, wherein positioning the stopper comprises applying a vacuum to the stopper.
2. The method of claim 1, wherein the primary packaging component is a syringe.
3. The method of claim 1, wherein the primary packaging component is a prefillable syringe.
4. The method of claim 1, wherein the primary packaging component is a prefillable syringe having a nominal volume of at least 1 mL.
5. The method of claim 1, wherein the volume of the formulated drug substance is at least 0.05 mL greater than the nominal volume of the primary packaging component.
6. The method of claim 1, wherein the formulated drug substance comprises one of a protein, a nucleic acid, or a gene therapy medicament.
7. The method of claim 1, wherein the formulated drug substance comprises an antibody and at least one excipient.
8. The method of claim 1, wherein the formulated drug substance comprises an antibody solution, wherein antibody is present in the solution at a concentration of at least 100 mg/mL.
9. The method of claim 1, wherein the formulated drug substances comprises an antibody, and has a viscosity of at least 5 cPoise.
10. The method of claim 1, further comprising placing the primary packaging component into additional packaging.
11. A method of preparing a plurality of drug products, the method comprising repeating the steps of claim 1 for each of a plurality of primary packaging components in a batch.
12. The method of claim 11, wherein the batch of primary packaging components comprises 80 prefilled syringes.
13. A drug product prepared by the method of claim 1.
14. The method of claim 1, wherein the primary packaging component is a prefillable syringe, the nominal volume is 1 mL, and positioning the stopper within the primary packaging component further comprises inserting the stopper into a body of the syringe such that an end of the stopper closest to a flange of the syringe is between about 2.5 mm and about 5.0 mm away from the flange of the syringe.
15. The method of claim 1, wherein the volume of the formulated drug substance is between 1.05 mL and 1.30 mL.
16. The method of claim 1, wherein the volume of the formulated drug substance is between about 110% and about 140% of the nominal volume of the primary packaging component.